

Amendment in Response to Office Action of October 10, 2007

REMARKS

Amendments to the Specification

The Examiner has objected to the Abstract because it does not meet the requirements of the MPEP for U.S. applications. Accordingly, an amended Abstract is provided herewith. Thus, Applicants respectfully request that the objection be removed.

The Examiner has requested that Applicants provide a "Cross-Reference to Related Applications." Accordingly, the specification has been amended herein to include the cross-reference to the related PCT and Japanese applications.

No new matter has been added by way of the amendments to the specification.

Status of Claims

Claims 1-9 were previously pending. Claims 1-2, 4-6, and 9 have been amended herein. Claims 3 and 7-8 have been cancelled herein. Claims 10-13 have been added. Claim 1 has been amended to add a proviso to exclude symptoms accompanied by alcoholism. Although Applicants' specification supports inclusion of such symptoms, such symptoms are excluded in an effort to advance the prosecution of this application. Support for the additional recitations in claim 1 can be found in claim 2 as originally filed.

Support for the newly added claims can be found in the specification at, *inter alia*, page 8, lines 18-30; page 9, lines 6-13; and claim 2 as originally filed. No new matter has been added by way of the above amendments or new claims.

General Comments Regarding Personal Interview

Applicants' Representative appreciates the courtesies extended by the Examiner during the personal interview on December 4, 2007. Claims 1-6 and 9 were discussed as well as some of the arguments presented herein. The Interview Summary Form summarizes the main points discussed at the interview. Although an agreement could not be reached, Applicants believe that the claims are now in condition for allowance. Should the Examiner believe that there remains any outstanding issues, Applicants respectfully request that the Examiner contact Applicants' Representative so as to expedite resolution of these outstanding issues, via an Examiner's Amendment or the like.

Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1-6 and 9 are rejected under 35 U.S.C. § 112, first paragraph, because the specification is not enabling. Applicants respectfully traverse, and reconsideration and withdrawal of these rejections are respectfully requested.

Applicants respectfully submit that the three kinds of experiments used in Examples 1 to 6 of the present specification have widely been known in this technical field as effective for testing anti-depressant effect of the compounds. When a compound was found to be effective by these experiments, it would be because of anti-depressant action and not by increase of energy. That is, according to the "Forced swimming test" as used in Examples 1 and 2 of the present specification, the test animals are in a state of despair or in a state of lowered mood (cf. Nature 266, p. 730-732 (1977), which is referred to in the present application at page 11, lines 6-7,

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particularly in said Nature, page 730, right column, line 3 from the bottom to page 732, left column, line 2 and page 732, left column, lines 57-59). When these states are removed or improved by administering a compound, it is considered that the compound exhibits anti-depressant action. This is also supported by the recent report of Neuroscience and Biobehavioral Reviews 29, p. 547-569 (2005), Abstract on page 547, lines 2-3 (see copy filed herewith).

Moreover, the "Reserpine-induced hypothermal competitive test" used in Examples 3 and 4 of the present specification is also well known in this technical field to be a test method for studying anti-depressant activity of a test compound (cf. Neuropharmacology 22(3), p. 267-272 (1983), which is referred to in the present application at page 13, lines 12-13, particularly in "Summary" on page 267, lines 3-4).

Thus, according to the tests in Examples 1 to 5 shown in the present application, D-ribose was effective, and hence, it is well supported that D-ribose can exhibit an anti-depressant activity. From these experimental results, any person skilled in the art will well understand that D-ribose can improve depression and depressive symptoms.

The anti-depressant activity of D-ribose was further proved by additional experiments as shown in the attached Declaration of Mr. Asahi, which reports the results of experiments that show that brain serotonin was changed by administration of D-ribose. The experimental results also show that D-ribose causes an increase of brain serotonin. In view of the above-mentioned recent report Neuroscience and Biobehavioral Reviews 29 p. 547-569 (2005), when a compound increases brain serotonin, it proves that the compound shows anti-depressant activity.

In the Declaration of Mr. Asahi, Mr. Asahi states that, on the basis of his knowledge and experience in this field, the experimental results disclosed in Examples 1 to 5 of the present application well support that D-ribose increases brain serotonin, and hence, D-ribose has an anti-depressant activity owing to the increase of the brain serotonin. Therefore, D-ribose is effective on various depressive symptoms as defined in claim 1.

"Depressive symptoms" include generally those diseases as mentioned in WHO/ICD-10, F32. The diseases specified in the proposed amended claim 1 are substantially the same as those mentioned in WHO/ICD-10, F32. Thus, it will be readily understood by any person skilled in the art that the method of the present invention comprising administering D-ribose to a subject will be useful for improving the depressive symptoms as defined in the amended claim 1.

It should also be noted that the depressive symptoms as defined in new claim 11, such as hypobulia, enervation, and feeling of malaise will be in the state of lowered mood as mentioned in the above literature, Nature 266, p. 730-732 (1977), and hence, effects of D-ribose on these symptoms as defined in new claim 11 are experimentally proved by the experiments of Examples 1 and 2 of the present application.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-3 and 7-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse, and reconsideration and withdrawal of these rejections are respectfully requested.

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With respect to the rejection relating to the definition of "depression-like symptoms" in claims 1 and 2, the term was amended to the well-accepted term "depressive symptoms" as mentioned above. Thus, Applicants respectfully submit that the amendment overcomes the outstanding rejection and that the rejection be removed.

With respect to the term "such as" in claim 2, this term was deleted, as suggested by the Examiner. Thus, Applicants respectfully submit that the amendment overcomes the outstanding rejection and that the rejection be removed.

With respect to the rejections of claims 3, 7, and 8, claims 3, 7, and 8 have been cancelled, which renders the rejections as to these claims moot.

Rejections Under 35 U.S.C. § 102

Claims 7-8 are rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Vazquez et al. '027. Claims 7-8 have been canceled herein. Thus, this rejection is rendered moot. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-6 and 9 are rejected under 35 U.S.C. § 102(a) and (e) as being anticipated by Vazquez '027. Claim 3 has been cancelled herein, which renders the rejection as to this claim moot. Applicants respectfully assert that Vazquez '027 does not disclose each and every element of independent claims 1 or 9. Therefore, Vazquez '027 does not anticipate or render obvious claims 1 and 9.

As explained above, the anti-depressive effects of D-ribose of the present invention was proved by the experiments in Examples 1-6 of the present description, and the anti-depressive

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activity of D-ribose has never been taught or even suggested by any prior art. The anti-depressive activity of D-ribose is not caused by an increase in stamina.

In stark contrast, Vazquez '027 teaches that D-ribose can be used to decrease body fat of humans performing weight-training exercise. The reference fails to teach a method for improving depressive symptoms or mental fatigue by administering an effective amount of D-ribose, as the present invention explicitly claims. Furthermore, Vazquez '027 fails to suggest an anti-depressive activity of D-ribose not caused by an increase in stamina.

Applicants therefore respectfully submit that at least claims 1 and 9, and those dependent thereon, clearly distinguish over Vazquez '027.

Rejections Under 35 U.S.C. § 103

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vazquez '027 in view of Palazzi '311. Claims 3, 7, and 8 have been cancelled herein, which renders the rejection as to these claims moot. With respect to the remaining claims, Applicants respectfully traverse, and reconsideration and withdrawal of these rejections are respectfully requested.

The present invention is concerned with a method for improving depressive symptoms by administering D-ribose to a subject in need thereof as defined in claims. None of the prior art teaches or even suggests such activity of D-ribose. Thus, it is respectfully submitted that the present invention is patentable over the cited references.

As discussed above, Vazquez '027 does not disclose each and every aspect of claims 1 and 9. Applicants respectfully submit that Palazzi '311 does not overcome the deficiencies of this reference.

To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (See MPEP 2143.03). As discussed above, the combination of references fails to teach or suggest all the claim limitations of independent claims 1 and 9, and those dependent thereon. Therefore, a *prima facie* case of obviousness has not been established, and withdrawal of the instant rejection is respectfully requested.

Applicants therefore respectfully submit that at least claims 1 and 9, and those dependent thereon, clearly distinguish over Vazquez '027 in view of Palazzi '311.

Newly Proposed Claims 10-13

Applicants have newly proposed claims 10-13 in an effort to more clearly define the scope of protection owed to Applicants. The cited prior art does not teach the anti-depressive activity of D-ribose. The prior art is limited to the use of D-ribose to decrease body fat with weight training.

Based on the reasons given above, Applicants therefore respectfully assert that claims 10-13 clearly define over the prior art of record, and an early action to this effect is earnestly solicited.

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Inquiries by the Examiner at the Interview

The feed CRF-1 for test animal used in the experiments shown in the Declaration of Mr. Asahi does not include any D-ribose, that is, D-ribose is not supplemented during the process for preparing the feed.

As is declared by Mr. Asahi in his Declaration, the U.S. Government has given neither "Minimum Daily Requirements" nor "Recommended Dietary Allowances" with respect to D-ribose.

As is also declared by Mr. Asahi in his Declaration, D-ribose will exhibit its activities after being taken up into the brain in view of the experimental results in Examples 1 to 4 disclosed in the present specification as well as the effects on variation of brain neurotransmitters shown in his Declaration and in Example 5 disclosed in the present specification.

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Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Gerald M. Murphy, Jr. (Reg. No. 28,977) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: MAR 10 2008

Respectfully submitted,

By: 

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